

REMARKS

Applicant respectfully requests reconsideration. Claims 14, 18-19, and 22-28 are pending and under examination in this application. By this amendment, Applicant is canceling claims 22-24 without prejudice or disclaimer. Claim 14 has been amended to remove the recitation of the cannabinoid CBC-V. Claims 18, 19, 26-28 have been amended to be consistent with the amendments made to claim 14. As a result, claims 14, 18, 19 and 25-28 are pending for examination with claim 14 being an independent claim.

No new matter has been added.

Rejections under 35 U.S.C. §112

Claim 14 is rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

Without conceding the correctness of the rejection, and merely to expedite prosecution, Applicant has amended claim 14 to remove the recitation of cannabichromene propyl analogue (CBC-V) for treating mood disorders. The Office Action indicates that the specification provides support “for the cannabis plant extract to contain 30% of the total cannabinoid content as CBC” (page 4 of the Office Action). Thus, the claim as amended satisfies the written description requirement.

Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. §103

Claims 14, 18-19, and 22-28 are rejected under 35 U.S.C. §103(a) as being unpatentable over Brooke et al. (U.S. Patent 6,328,992) in view of Travis (U.S. Patent 6,541,510) and Turner et al. (J. Clin Pharmacol 1981; 21:283S-291S).

According to the Examiner, “it would have been obvious to a person of ordinary skill in the art [...] to treat mood disorders such as depression with cannabichromene compounds because of the teachings of Brooke et al. that cannabichromenes are useful in treating such disorders as depression” (page 5 of the Office Action). The Examiner also contends that it would have been

obvious “that the CBC amount would be higher because of the teachings of Turner that CBC is the major cannabinoid in freshly harvested drug-type cannabis material, which would make the amount of 30% obvious” (page 5 of the Office Action).

Applicant respectfully disagrees and submits that the Examiner has not met the requirements set forth in MPEP 2143 to establish a *prima facie* case of obviousness. MPEP 2143(A) states that to reject claims as obvious based on a rationale of combining prior art elements according to known methods to yield predictable results, “Office personnel must articulate the following:

(1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference;

(2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely performs the same function as it does separately;

(3) a finding that one of ordinary skill in the art would have recognized that the results of the combination were predictable; and

(4) whatever additional findings based on the Graham factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.”

MPEP 2143 states that, “[i]f any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.”

The Examiner did not establish that the prior art includes each element claimed, as required under MPEP 2143 A(1). The prior art cited by the Examiner lacks at least two elements recited in the instant claims as amended. First, as acknowledged by the Examiner on page 4 of the Office Action, Brooke et al. does not teach that cannabichromene (CBC) is present as more than 30% of the cannabinoids in the composition, as instantly claimed. Second, Brooke et al. does not teach that CBC is useful for treating mood disorders. Brooke et al. recites that “[s]everal medicinal uses have been found for the active ingredients of cannabis, including the ingredients tetrahydrocannabinol (THC), cannabinal (CBN), cannabidiol (CBD) and cannabichromene (CBC)” (col. 1, lines 23-26, emphasis added). Brooke et al. further discloses that the medicinal uses of cannabis include, among

a list of ten applications, stress and depression. Brooke et al. also states that THC is the “primary active ingredient of cannabis” (col. 1, lines 42-44). Applicant respectfully asserts that Brooke et al. makes no comment on the activity of each of the specified ingredient of cannabis. In particular, Brooke et al. does not teach that CBC is useful for treating mood disorders. Applicant respectfully submits that merely because cannabis is taught to have a number of medicinal uses, and CBC is listed as one of the active ingredients, it does not follow that CBC is useful for treating all disclosed indications. Indeed, as indicated in response to the previous Office Action dated March 11, 2009, at least 66 different cannabinoids have been isolated from the cannabis plant, and there is no expectation that each of these cannabinoids can treat all disclosed indications. Without further guidance, the skilled person would not have any expectation that any specific cannabinoid can be used to treat any one of the specific indications.

The Travis reference and the Turner et al. reference do not provide the elements of the claims that are absent from Brooke et al. Travis et al. teaches CBC containing compositions as anti-virals, and makes no mention of the ability of CBC to treat mood disorders or that CBC is present as more than 30% of the cannabinoids in the compositions. Turner et al. is cited for its asserted teaching that “cannabichromene is a crude drug made from cannabis plants”, and that “CBC is the major cannabinoid in freshly harvested drug-type cannabis material, which would make the amount of 30% obvious” (page 5 of the Office Action). Applicant respectfully disagrees and maintains that CBC is not abundant in most mature cannabis plants. A sampling of the cannabinoid composition during the life cycle of several cannabis plants reveals that the proportion of CBC in the total cannabinoid fraction decreases with ageing of the plant (see, e.g., pages 19-20 and Figures 3A-C of WO 2009/125198, cited in the Information Disclosure Statement submitted herewith). Most cannabis plants are bred specifically for high and predominant THC content, and as a result, the second most abundant cannabinoid in most mature cannabis plants may comprise less than 2% of the total cannabinoids. Accordingly, there is no teaching in Turner et al. which would render obvious the use of a plant extract comprising greater than or equal to 30% CBC for treating a mood disorder. The combined teachings of Brooke et al., Travis and Turner et al., thus, do not contain each element of treating a mood disorder in a human patient with CBC that is substantially pure or

is an extract from a cannabis plant containing greater than or equal to 30% CBC of the total cannabinoid content.

Additionally, the rejection fails because the Examiner did not establish that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely performs the same function as it does separately, as required under MPEP 2143 A(2). As discussed above, the cited art does not contain each element of the claimed invention and, thus, the skilled artisan could not have arrived at the current invention by combining the cited art. Further, the observation that the proportion of CBC reduces in mature plants, and the difficulties associated with developing high CBC producing cannabis plants make it unlikely that one of ordinary skill in the art could have combined the elements as claimed by known methods.

Further, the rejection fails because the Examiner also did not establish that one of ordinary skill in the art would have recognized that the results of the combination were predictable, as required under MPEP 2143 A(3). As discussed above, at least 66 different cannabinoids have been isolated from the cannabis plant. Absent some teaching pointing to specific cannabinoids, the skilled person would not have known which one or more cannabinoids would be useful in treating mood disorders, and would not have had a reasonable expectation of success in randomly selecting cannabinoids to try. Brooke et al. teaches that “cannabis” (and not CBC) can be used for potentially treating a number of medical indications. Similarly, neither Travis nor Turner et al. teach or suggest using CBC for treatment of a mood disorder. The skilled person would not have been motivated to make the claimed invention due to the link between cannabis and depression in the art as was stated in the Whittle Declaration filed on December 1, 2008 (see paragraph 11c). Dr. Whittle also stated that the skilled person would not have had a reasonable expectation of success in making the claimed invention for this same reason.

The MPEP states that the fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness. MPEP 2144.08 II, citing In re Baird, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994). Therefore, absent some indication in the prior art that cannabichromene in particular is useful for treating mood

disorders, the claims are not obvious in view of combination of Brooke et al., Travis and Turner et al.

In view of the Examiner failing to convincingly support at least three out of four findings as required by MPEP 2143 A to establish a *prima facie* case of obviousness for at least the above discussed reasons, Applicant respectfully requests the rejection of claims 14, 18-19, and 22-28 under 35 USC §103 on these grounds to be withdrawn.

Claims 14, 18-19, and 22-28 are rejected under 35 U.S.C. §103(a) as being unpatentable over Whittle et al. (US Pg/Pub 2005/0042172) in view of Turner et al. (J Clin Pharmacol 1981; 21:283S-291S).

The Examiner states at page 7 of the Office Action that it would have been obvious to treat mood disorders such as depression with cannabichromene compounds because Whittle et al. allegedly teaches that cannabichromenes are useful for treating disorders such as pain associated with depression, which necessarily treat depression. Applicant respectfully disagrees.

Paragraph [0056] in Whittle et al. is the only passage that mentions depression at all. It states that compositions comprising cannabis extracts, natural or synthetic cannabinoids or mixtures thereof can be administered “in the form of a vapour for the treatment of pain, particularly pain unresponsive to opioid analgesics, pain arising from neuropathic and neurogenic conditions, dysmenorrhoea, inflammatory pain, particularly that associated with rheumatoid arthritis, depression, migraine, asthma, epilepsy, post-operative pain, glaucoma, chemotherapy-induced nausea and vomiting, relief of pain and muscle spasm in multiple sclerosis, and loss of appetite and anorexia, particularly in AIDS patients.” Like Brooke et al., Whittle et al. does not link any specific cannabinoid to treatment of depression, and more importantly, does not link the use of CBC to treatment of depression. Applicant respectfully submits that merely because compositions comprising cannabis extracts are taught to have a number of medicinal uses, it does not follow that CBC is useful for treating all disclosed indications let alone for treating a mood disorder, which is not specifically described in Whittle et al. Indeed, as indicated in response to the previous Office Action dated March 11, 2009, at least 66 different cannabinoids have been isolated from the cannabis plant, and there is no expectation that each of these cannabinoids can treat all disclosed indications. Absent some teaching pointing to specific cannabinoids, the skilled person would not

have known which one or more cannabinoids would be useful in treating mood disorders, and would not have had a reasonable expectation of success in randomly selecting cannabinoids to try.

Also, as acknowledged by the Examiner on page 6 of the Office Action, Whittle et al. does not teach that the CBC extract contains greater than or equal to 30% CBC of the total cannabinoid content. As discussed above, there is no teaching in Turner et al. which would render obvious the use of a plant extract comprising greater than or equal to 30% CBC for treating mood disorder. CBC is not abundant in most mature cannabis plants and a sampling of the cannabinoid composition during the life cycle of several cannabis plants reveals that the proportion of CBC in the total cannabinoid fraction decreases with ageing of the plant (see, e.g., pages 19-20 and Figures 3A-C of WO 2009/125198, cited in the Information Disclosure Statement submitted herewith). Most cannabis plants are bred specifically for high and predominant THC content, and as a result, the second most abundant cannabinoid in most mature cannabis plants may comprise less than 2% of the total cannabinoids. The combined teachings of Whittle et al., and Turner et al., thus, do not contain each element of treating a mood disorder in a human patient with CBC that is substantially pure or is an extract from a cannabis plant containing greater than or equal to 30% CBC of the total cannabinoid content. Thus, the skilled artisan could not have arrived at the current invention by combining the cited art.

The Examiner has also failed to establish that one of ordinary skill in the art would have recognized that the results of the combination were predictable. Neither Whittle et al. nor Turner et al. teach or suggest using CBC for treatment of mood disorders. The skilled person would not have been motivated to make the claimed invention due to the link between cannabis and depression in the art as was stated in the previously-filed Whittle Declaration (see paragraph 11c). Dr. Whittle also stated that the skilled person would not have had a reasonable expectation of success in making the claimed invention for this same reason.

In view of the Examiner failing to convincingly support at least three out of four findings as required by MPEP 2143 A to establish a *prima facie* case of obviousness for at least the above discussed reasons, Applicant respectfully requests the rejection of claims 14, 18-19, and 22-28 under 35 USC §103 on these grounds to be withdrawn.

Double Patenting Rejection

Claims 14-15, 18-25, and 27-28 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 12, and 14 of copending Application No. 11/760,364.

Applicant notes that claims 2 and 4 of co-pending Application No. 11/760,364 have been cancelled. The instant claims have been amended to recite methods for treating mood disorders by administration of CBC, wherein the CBC is substantially pure or is an extract from a cannabis plant that contains greater than or equal to 30% CBC of the total cannabinoid content

The claims in US 11/760,364 have been amended to recite administration of an entirely different cannabinoid, cannabigerol (CBG), which is structurally different than the compound recited in the claims as amended of the instant application. Applicant maintains that the use of CBC for treating mood disorders is not obvious in view of the use of CBG in US 11/760,364.

Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. H0664.70032US00.

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Respectfully submitted,

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